PATENT – DOCKET NO. 1502-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	William F. McKay et al.	Examiner:	Brian E. Pellegrino
Serial No:	10/666,900	Art Unit:	3738
Filed:	September 18, 2003	Conf. No.:	8517
For:	**NATURAL TISSUE DEVICES AND METHODS OF IMPLANTATION**	Date:	March 22, 2010

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PRE-APPEAL BRIEF

This Pre-Appeal brief is submitted with a Notice of Appeal in response to the Final Office Action mailed January 22, 2010 by the U.S. Patent and Trademark Office in the above-identified application. It is respectfully asserted that the rejection of Claims 17-19, 27 and 45-47, 49 and 50 under 35 U.S.C. § 112, first paragraph, as lacking enablement is improper and it is respectfully requested that the rejection be reconsidered and withdrawn for the reasons stated herein. In addition, the rejection of the claims under 102 and 103 in view of the cited art is also improper and for the reasons stated herein should also be withdrawn. Accordingly, this response is filed timely upon mailing with an executed Certificate of Mailing on or before March 22, 2010 and is accompanied by a Notice of Appeal and requisite fees. It is believed that this response does not occasion any additional fees or extensions of time, but should there be any need for such an extension of time please treat this paper as such and charge (or credit) any extension fees, or any additional fees that may be due herein, to Deposit Account No. 04-1121.

CERTIFICATE OF EFS-WEB TRANSMISSION

I hereby certify that this correspondence is being transmitted to the U.S. Patent and Trademark Office via the Office's electronic filing system on the date indicated below.

Dated: March 22, 2010

Leo G. Lenna

REMARKS

Claims 17-19, 27, 45-47 and 49-58 are pending in the application. In the Final Office Action mailed January 22, 1010, Claims 17-19, 27, 45-47 and 49 and 50 have been rejected under 35 U.S.C. § 112, first paragraph. In making the rejection, the Examiner stated that Claims 17-19, 27 and 45-47, 49 and 50 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled since the specification allegedly does not enable one skilled in the art to restrain the tissue during the pulling of the drawstring to fold the tissue so as to prevent the tissue from being pulled in the drawstring-pulling direction.

However, as stated in the previous response, it is well known that Applicants' specification can only be said to lack enablement for the aforementioned restraining operation (recited in step (c) of the claims) if such were to require "undue experimentation". As held by the court in *In re Wands*, 858 F.2d 732, 8 USPQ3d 1400, 1404 (Fed. Cir. 1988), any analysis of what constitutes "undue experimentation" must take into account at least the following 8 case-dependent factors: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

When all of these *Wand* factors are considered, it is clearly evident that those skilled in the art, in this case, knowledgeable, experienced orthopedic surgeons, would very soon, if not immediately, grasp from the implantation procedure illustrated in stages in Figs. 7-10, that pulling on the drawstring without at the same time preventing the implant from being pulled in the drawstring-pulling direction will fail to achieve the result illustrated in Fig. 10. It would take very little further reflection on this situation by an orthopedic surgeon to realize that all that is needed to prevent the tissue from being pulled in the drawstring-pulling direction during each pulling of the drawstring is for the second end of the tissue to be held stationary while pulling of the drawstring causing the first end of the tissue to fold, eventually forming the pleated implant illustrated in Fig. 10. The surgeon's hands and/or a standard surgical utensil are well-suited to simultaneously holding the implant stationary and pulling on the drawstring.

Applicants submit that when the sufficiency of the specification as an enabling disclosure is evaluated in accordance with the *Wand* factors, it can only be concluded that no undue experimentation would be required of an orthopedic surgeon in order to carry out step (c) of the method of Claim 27 and claims dependent thereon. For these reasons, the rejection of Claims 17=19, 27, 45-47 and 49-58 must be withdrawn.

In the Final Office Action, the Examiner has repeated nearly *verbatim* his previous rejection of Claims 51-53 and 56-58 as allegedly being anticipated 35 U.S.C. § 102(a) by Gabbay.

As stated in the previous response, by further amplifying the distinctions between Gabbay's suture 50 and Applicants' drawstring and drawstring operation as

presented in Applicants' previous traverse of this rejection, Applicants wish to emphasize the disparity in function between suture 50 illustrated in Gabbay Figure 4 and the drawstring component of Applicants' claimed intervertebral disc device. Gabbay states as the only function of suture 50 that it be used to permanently or temporarily sew overlapping layers 48 of tissue material constituting prosthesis 46 together. Suture 50 is not intended to be pulled so as to bunch any tissue layer or layers together in the form a pleated structure. Forming a pleated structure is not within the purview or contemplation of the Gabbay disclosure.

In order to perform its function as a drawstring and as illustrated in Figs. 7-10, drawstring 72 must be *secured* at or near first end 74 of tissue implant 71. This feature of being "secured" is required in order to prevent drawstring 72 from being pulled or drawn away from first end 74 of implant 71 during the pulling operation. There is no comparable showing of a "secured" suture 50 in Gabbay.

Moreover, an additional feature of Applicants' drawstring 72 that is required for it to function as a drawstring is that there be an end portion 73 of drawstring 72 which extends beyond second end 75 of tissue implant 71 and which is adapted to being pulled. There is no comparable showing of suture 50 in Gabbay Fig. 4 as possessing an end portion extending beyond tissue layer(s) 48 much less such an end portion adapted to being pulled.

For the reasons presented in Applicants' previous traverse of this rejection and for the further reasons presented here, the intervertebral disc device of Claims 51-53 and 56-58 is considered to be novel (and nonobvious) over Gabbay and the rejections must be withdrawn.

In the Final Office Action the Examiner has again rejected Claims 54 and 55 for obviousness (35 U.S.C. § 103(a)) over the combined disclosure of Gabbay and Sybert et al. The remarks stated above concerning Gabbay equally apply here as well.

In view of the reasons presented above, independent Claim 51 is considered to be patentable over Gabbay alone and Claims 54 and 55 depending therefrom are also considered to be patentable over both Gabbay and the combined teaching of Gabbay in view of Sybert et al. A review of Sybert et al. clearly shows that it fails to correct the factual deficiencies of Gabbay and therefore the combined disclosures of Gabbay and Sybert et al., the latter reference merely disclosing an implant made from natural tissue and provided as a braided construction, fails to teach or suggest the claimed invention.

Moreover, as discussed in the previous response, the invention of dependent Claims 54 and 55 resides in the unique drawstring feature of independent Claim 51 and the singular structural relationship of the drawstring to its associated natural tissue implant enabling the implant to assume a pleated configuration when fully implanted within a disc nucleus space. There is nothing in the combined disclosures of Gabbay and Sybert et al. that so much as even hints at these features. Such being the case, Claims 54 and 55 are considered to be nonobvious, and therefore patentable, over Gabbay combined with Sybert et al. Accordingly, it is respectfully requested that the rejection be withdrawn.

In the Final Office Action, the Examiner has maintained the rejected Claims 17, 18, 27, 45-47, 49 and 50 as allegedly being obvious (35 U.S.C. § 103(a)) over Muhanna in view of Lambrecht et al.

In making the rejection, the Examiner correctly characterizes ribbon 16 of Fig. 4B of Muhanna as having a "pleated" structure, i.e., an accordion-like or bellows-like configuration, and then points to twice folded sheet 14 of Fig. 3A for its disclosure of a tissue structure possessing what is referred to as "drawstring 15." For one thing, the tissue structure of Fig. 3A is not a pleated structure as is the tissue structure shown in Fig. 4B of the present invention and recited in the claims. For another, element 15 of the structure shown in Fig. 3A is described by Muhanna as a "first fastener" which indeed it is. First fastener 15 of Fig. 3A is not a drawstring and cannot function as a drawstring. It is, as Muhanna describes it, only a fastener.

Applicants' claimed method (Claim 27) calls for implanting a length of natural tissue which possesses an initial first, straightened configuration and a second, folded, or pleated, configuration. In both configurations, the tissue possesses a drawstring secured to one end, extending beyond the opposite second end and coursing through the tissue at intervals from one side to the other. If one were to lay out twice folded sheet 14 of Muhanna Fig. 3A in its original (first) straightened configuration, it would be abundantly evident that fastener 15 (untied to permit sheet 14 to assume its straightened configuration) is not secured to one end of sheet 14, does not extend beyond the opposite end of sheet 15 and does not course through sheet 14 at intervals from one side to another.

In short, there is nothing in Muhanna that even remotely resembles Applicants' drawstring and its mode of operation. Recognizing this, the Examiner relied on the disclosure of Fig. 49G of Lambrecht et al. for its illustration of an implant 400 possessing guide filament 406. Moreover, the Examiner continues to maintain that guide filament 406 functions as a drawstring. However, as Applicants' in their previous traverse of this rejection have explained at length, Lambrecht et al. control filament 406 (also referred to therein as "guide filament 406") does not, and cannot, function in the same manner as Applicants' drawstring. The Examiner has yet to respond to the specific points of difference between Lambrecht et al. guide filament 406 and the drawstring and mode of operation of the drawstring raised by Applicants in their previous traverse. These points of difference are restated and amplified as follows:

(1) unlike Applicants' drawstring, Lambrecht et al. control filament 406 does not pass through a multiplicity of sites;

(2) unlike Applicants' drawstring, Lambrecht et al. control filament 406 does not pass through the tissue implant from one side thereof to another along the length of the tissue;

(3) unlike applicants' drawstring, pulling on Lambrecht et al control filament 406 will not result in an implant having multiple pleated folds; and,

(4) the function and purpose of Lambrecht et al. control filament 406 are illustrated in the sequence of drawings 49A through 49G and are explained in paragraphs 0207 and 0208; there is not the slightest suggestion anywhere in this or any other drawing(s) or text of Lambrecht et al. that pulling on control filament 406 will cause implant 400 to assume a pleated configuration.

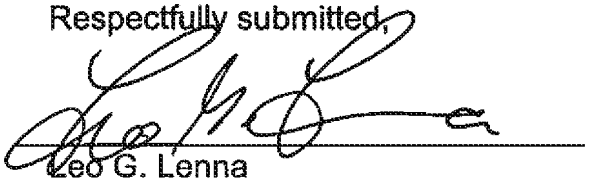
These differences clearly show that the combination of the cited references fall far short of what is claimed. Moreover, the Examiner has failed to even address four specific points of difference in the Final Office Action. For this reason, it can only be assumed that no rebuttal is possible. Based on these differences, as well as the remarks presented herein, the rejection of Claims 17, 18, 27, 45-47, 49 and 50 must be withdrawn.

Finally, in a separate rejection, the Examiner has rejected dependent Claim 19 (which specifies that in the method of independent Claim 27, the tissue be that of a small intestine submucosa) as obvious (35 U.S.C. § 103(a)) over Muhanna in view of Lambrecht et al. as applied to Claim 27 and further in view of Sybert et al.

All of the above mentioned remarks evidencing the patentability of independent Claim 27 equally apply to this rejection as well. For all of the above reasons, Claim 27 is patentable over the combined disclosures of Muhanna and Lambrecht et al. In addition, Claim 19 is also considered to be patentable over these references further combined with Sybert et al., the last mentioned reference doing nothing to make up for the absence in the combined disclosures of Muhanna and Lambrecht et al. of Applicants' drawstring feature and its mode of operation. In view of the foregoing, the rejection of Claim 19 must also be withdrawn.

In view of the foregoing remarks, all rejections in the Final Office Action mailed January 22, 2010 are improper and must be withdrawn. Accordingly, allowance of pending Claims 17-19, 27, 45-47 and 49-58 is respectfully requested.

Respectfully submitted,



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